



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/818,260	03/26/2001	Nicholas J. Schork	G-085US04CON	9223
23557 7590 01/07/2009 SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950				
EXAMINER				
LIN, JERRY				
ART UNIT		PAPER NUMBER		
1631				
MAIL DATE		DELIVERY MODE		
01/07/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/818,260

Applicant(s)

SCHORK ET AL.

Examiner

JERRY LIN

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4, 7, 40, 41 and 46-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 7, 40, 41, 46-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/C)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date: _____

DETAILED ACTION

1. Applicants' arguments, filed September 22, 2008, have been fully considered and they are deemed to be persuasive in part. However, in light of recent court decisions, a new rejection is also deemed necessary. The following rejections constitute the complete set presently being applied to the instant application.

Status of the Claims

Claims 1, 4, 7, 40, 41, and 46-50 are under examination.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 7, 40, 41, 48, 49 and 50 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Instant claims 1, 40, 41 and 50 are drawn to a method of determining the statistical significance of a difference between haplotype frequency profiles. However, as the method does not recite a physical transformation of matter, the method must be tied to a machine to be patentable subject matter (For further explanation see, *In Re Bilski* (No. 2007-10030, decided 10/30/2008)). In the instant case, the claimed method steps are not tied to a machine, and thus are non-statutory.

Instant claims 7, 48, and 49 are drawn to a computer program embodying a process involving the judicial exception of a computational algorithm. Claims drawn to a judicial exception is non-statutory unless the claims include a practical application of that judicial exception. A practical application may be demonstrated by a physical transformation of matter or if the claimed invention recites a useful, tangible and concrete final result. In the instant claims, there is no physical transformation by the claimed invention, thus the Examiner will determine if the instant claims produce a useful, tangible, and concrete final result.

The instant claims do not produce a useful, concrete, and tangible final result. A useful, concrete, and tangible final result requirement requires that the claim must set forth a practical application of the mathematical algorithm to produce a real-world result. The last step is one of determining the significance. However, there is no indication that a result is necessarily produced or that the result is communicated to the outside world. Since there is no final result in the claims, the instant claims do not include a useful, concrete, and tangible final result. Examples of amendments to overcome this rejection include amending the claims to identify/recite a concrete result and to recite that the result is outputted to a display or to a user or outputted in a user readable format. However, applicant is reminded that any amendment must be fully supported and enabled by the originally filed disclosure.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 4, 7, 40, 41, and 46 - 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stanton, Jr. (US 2002/0039990) in view of Kidd et al. (Human Genetics (1998) Volume 103, pages 211-227) and in view of Jeffreys (US 5,811,235).

Stanton, Jr. teaches a method of determining the statistical significance of a difference between haplotype frequency profiles of at least two groups of individual which includes determining the combined likelihood that the two groups of individuals are derived from the same distribution of haplotypes, determining the sum of the separate likelihoods that each of the two groups of individuals are derived from the same distribution of haplotypes, and determining the difference of the sum and combined likelihood (page 65, paragraph 0825).

Stanton, Jr. does not teach obtaining the haplotypes of individuals for each group by genotyping the same chromosome, randomly permuting the haplotypes between groups to determine the probability that the groups do not come from the same distribution of haplotypes, or calculating all possible single-haplotype chi-square tests. Nor does Stanton teach using a binary code to identify the haplotypes of all individuals.

Kidd et al. teach a method of determining the haplotype frequencies of a population which include obtaining haplotypes for all individuals in each of two groups of individuals by genotyping the same gene which is located on the same chromosomal segment (Page 212, right column, bottom - page 213); randomly permuting the haplotypes between groups to determine the probability that the groups do not come from the same distribution of haplotypes (page 213, right column; page 216); assessing the statistical significance of individual haplotypes using a P-excess value (page 224). Regarding claim 40 in particular, Kidd et al. teach calculating all possible single-haplotype chi-square tests (page 224).

Jeffreys teaches a method of characterizing genomic DNA which includes providing binary codes for an allele or a haplotype (column 2, lines 38- column 3, line 7); and using that code to generate an array (column 16, lines 38-43, Fig. 1A).

Stanton teaches implementing his methods using computer programs and computer storage devices including outputting results to a storage or display (Stanton, page 65, paragraph 0825; page 45, paragraph 0512).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the references of Stanton, Kidd et al., and Jeffreys to gain the

benefit of creating a computer system for comparing frequencies and establishing the correlations between a phenotype and genotype. Kidd et al.'s methods provide the advantage of determining the statistical significance of a correlation between a phenotype and genotype (Kidd et al., page 213) which would supports Stanton's stated goal of identifying variances within genes (Stanton, page 1, paragraph 0006). In addition, Jefferys states that a system of generating a large number of unambiguous DNA phenotypes in a database would be advantageous for comparing frequencies and would require binary coding (Jefferys, column 2, line 38-65). Thus, one of ordinary skill in the art would have been motivated to add Jefferys's method to binary coding of alleles to the above references (Stanton, page 65, paragraph 0825). Furthermore, since all the methods are computational, one of ordinary skill in the art would have a reasonable expectation of success in combining the above reference.

Response to Arguments

5. Applicants have responded to this rejection by amending the claims to include the step of coding all haplotypes with binary masks arrays and grouping identical genotypes with an array. It is noted on page 22 of the Specification, the applicants do describe their method of coding haplotypes. However, the instant claims broadly recites coding all haplotypes with binary masks arrays and is not limited to the method of coding described in the specification. Jefferys does teach binary coding for haplotypes (column 2, lines 38- column 3, line 7) and grouping genotypes with an array (column 16, lines 38-43, Fig. 1A). Thus the cited references do teach the new limitations.

Withdrawn Rejections

6. Applicant's arguments and amendments, filed September 22, 2008, with respect to the rejection of claims 4, 46, and 47 under 35 U.S.C. §101 as non-statutory, have been fully considered and are persuasive. The instant claims have been amended to include a tangible final result and the claims are tied to a machine. This rejection has been withdrawn.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY LIN whose telephone number is (571)272-2561. The examiner can normally be reached on 7:00-5:30pm, M-TH.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie A. Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jerry Lin/
Examiner, Art Unit 1631
12/24/08